Chapter 5 General discussion

In this part a comparison between the clinical and the laboratory study will be made. In addition, we will attempt to explain the differences and give future directions

5.1 Comparison between clinical and laboratory results

First of all, it should be remarked that it is hard to compare results obtained in the laboratory, a non-physiological situation where several parameters are fixed, and results obtained in practice, where many different, uncontrollable, parameters play a role in shunt functioning.

In the clinical situation, only a minor part of the number of shunt dysfunctions was caused by valve problems. On the other hand, the laboratory results indicate that about half of the valves did not perform according to the manufacturer's specifications. In addition to that, all valves except the Hakim valve were sensitive to eryhtrocyte counts above 5000 cells/µl. Particularly the Orbis Sigma valve showed a tendency to obstruction with erythrocyte perfusion in the laboratory situation. Our laboratory results do not impose a contra-indication for shunt insertion in CSF containing high protein levels. We were not able to test the influence of high erythrocyte counts on shunt functioning in the clinical situation. Ninety percent of the patients had erythrocyte counts below 5000 cells/µl. Apparently, neurosurgeons decide not to insert shunts if the patient's CSF contains a high erythrocyte count. Shunts incorporating the Orbis Sigma valve actually showed less dysfunction in children under one year of age, whereas in older age groups there was no difference between the valves. In the clinical setting, it was in fact the Raimondi valve that showed the highest revision rate.

The best explanation for this discrepancy between the laboratory and clinical results is probably the already mentioned difference between testing in vitro in a laboratory situation and the actual situation in vivo. Aschoff[7,13] stated that whereas approximately 80% of the valves showed overdrainage both during testing and in a clinical situation, the clinical results of shunting are usually sufficient. Either the patients may be only partially shunt- dependent, or people in general are able to adapt to unphysiological low intracranial pressure in an upright position. Aschoff particularly stresses the enormous adaptability of the patients. In poor countries shunting usually takes place through an open ventriculoperitoneal tube without a valve[7]. In fact, these systems may be the most frequently implanted worldwide. Although this system does not incorporate an anti-reflux design,

and the flow rates are excessive, until now only subtle clinical differences from valve-incorporating shunts have been proven[7]. The Poisseuille equation shows that the internal diameter of the silicone tubes is very important in determining the total shunt resistance: the equation includes the internal diameter in the fourth exponent. Actually, about 80 % of the total shunt resistance is determined by the tubes, whereas the resistance of the valve is only a minor part of the total resistance. Less important are length and viscosity. Therefore, reducing the diameter of the tubes may be a reasonable option for reducing overdrainage in CSF shunting in the clinical situation. Aschoff[7,8] suggested to reduce the internal diameter from the current 1.3-1.1 mm to 0.8-0.9 mm. According to him this would be an acceptable compromise between a more effective flow-control and the necessary obstruction-reserve.
The question could be, mainly after reviewing the clinical study: 'Does a shunt system actually need a valve to function properly in a patient?' If we would not set our standards of shunt functioning too high, the answer could be no. However, according to Aschoff[7,8,13] there is a residual 20% of the patients which does need high-tech valves with an exact function and a perfect compensation of postural pressure changes. Furthermore, for all patients we should strive for the optimal CSF shunting system, even small advantages of valve-use are valuable if they improve the patient's quality of life. In the clinical situation, the best option would be a shunt system with a smaller internal tube diameter including a programmable valve or a hydrostatic valve, or alternatively, an Orbis Sigma-like valve with a slightly increased outlet diameter which would not be as prone to obstruction as the current valve. Our study shows that an exception should be made in the youngest age group. In this group we showed that significantly less revisions were necessary in cases were the Orbis Sigma valve was used.

5.2 Future recommendations

Although CSF shunt surgery has improved greatly over time, it is still a treatment that harbours many complications.
Aschoff [7,8,13] posed several criteria for a satisfactorily functioning shunt system:

* a shunt should maintain the intracranial pressure within the physiological range, independent on body position or temporary increases in abdominal pressure. It should also be able to withstand CSF containing protein or debris
* a shunt should be highly biocompatible, durable and insensitive to external pressure

Our clinical study confirmed other studies, by showing that proximal catheter obstruction is the most frequent cause of shunt malfunctioning. In addition, we reported a correlation between a short ventricular catheter length and obstruction. A recommendation for the future could be to use ventricular catheters with a minimal length of 6 to 7 cm, depending on the age of the patient.

In *The Shunt Book*[43] Drake and Sainte-Rose stated that today no other materials could replace silicone elastomers in their wide medical applications. Silicone has been found to be an inert material, with minimal reaction of the biologic system to its presence. In a recent report Kalousdian et al.[70] reviewed all the articles that reported immunological reactions in patients with silicone CSF shunt systems. Over a period of 30 years, they only found five journal articles that described possible immunological reactions on CSF shunts. The evidence presented did not support the occurrence of immune-mediated systemic reactions to implanted silicone elastomer CSF shunts. In support of the American Medical Association, they stated in 1993[3], that since each molecular species may have differing potential for biological mobility and activity, it is mandatory to evaluate each product for safety and to avoid inappropriate extrapolations among differing chemical entities. Therefore, the controversies that have surrounded *silicone gel-filled* breast implants are not relevant to the safety of *silicone elastomer* shunts. However, multiple clinical problems still exist due to certain applications of silicone products. The problems are related to its surface properties[62]: in the blood, thrombi will form around silicone implants, which may dislodge and cause symptoms around the implants. In addition, scar formation may occur, and in the eyes, where transparencies are needed as in the intraocular lens implant, the scar interfaces with the visual image transmissions. Schoener[113] conducted a study on 36 explanted shunts and reported that 61 % of the shunts showed defects which led to tissue migration into shunt lumens or to tissue adherence to the tube surface. In every case of tube obstruction, he found calcification and destruction of the silicone elastomer tubing. Brydon[23,24] reported that more than 80 % of explanted valves containing metallic parts in their construction had internally accumulated debris, whereas only 25 % of non-metallic valves showed accumulation of debris. According to Habal[62], some of these internal problems relate to the hydrophobic nature of the silicone surface. In certain clinical applications, these problems have been resolved in part by adsorbing a wetting agent, such as povidone, to the surface. Such obviation has gained wide clinical application in surface coating of the intraocular lens. Habal states that ‘In search of an ideal implantable material, silicone, the most applicable, is still far from being called the ideal implant. Perhaps with the changes of its surface properties, such as introducing wetting agents to its surface, a new dimension in clinical applications will open the horizons of silicone in the 1980’s’. However, 14 years after this statement, shunt obstruction is still the most frequently found complication after shunt surgery, which indicates the importance of biocompatibility of the shunt materials. Further research will be necessary to improve the biodurability and biocompatibility of CSF shunt systems.

As mentioned above, a way to reduce overdrainage could be to use tubes with a reduced internal diameter together with a conventional valve, or to use an Orbis Sigma valve with a slightly larger outlet, which is not as sensitive to obstruction as the current Orbis Sigma valve.

In the youngest age group, we would like to recommend the use of the Orbis Sigma valve. This valve gave significantly less complications in children under one year of age.

Although the shunt infection rate is rather low in the Netherlands compared to other countries, it would still be useful to aim preventive measures at high-risk patients, who can mainly be found in the youngest age group. Shunt impregnation with antibiotics may be a useful method here.

In the clinical chapter we quoted Rekate[106] who stated :'The best shunt is no shunt'. Indeed, further improvement and use of the endoscopic techniques will decrease the need for shunts in the future. However, in the near future, shunts will still be widely used in the treatment of hydrocephalus.

In the clinical chapter we already mentioned the importance of the quality of life in the evaluation of shunt functioning. If the patient's quality of life is excellent, in spite of several shunt revisions, the evaluation of shunt surgery should be positive in stead of negative, which it would have been in the current studies. Future studies should include the patient's quality of life as an important parameter in the evaluation of shunt functioning.